

## REMARKS

### Status of the Claims:

1. (Canceled)
2. (Canceled)
3. (Canceled)
4. (Canceled)
5. (Canceled)
6. (Canceled)
7. (Canceled)
8. (Canceled)
9. (Canceled)
10. (Canceled)
11. (Canceled)
12. (Canceled)
13. (Canceled)
14. (Canceled)
15. (Canceled)
16. (Canceled)
17. (Canceled)
18. (Canceled)
19. (Canceled)
20. (Canceled)
21. (Canceled)

22. (Previously Presented) The cardiovascular healthcare management system of claim 38 further comprising a physician data access interface to allow physician access to the infomediary databases.

23. (Previously Presented) The cardiovascular healthcare management system of claim 38 further comprising a communication system allowing the physician to communicate cardiovascular healthcare management information to the patient.

24. (Previously Presented) The cardiovascular healthcare management system of claim 38 further comprising a cardiovascular knowledge base that stores information related to cardiovascular risk factors.

25. (Previously Presented) The cardiovascular healthcare management system of claim 38 wherein the diagnostic engine includes algorithms for associating test results with possible treatments.

26. (Previously Presented) The cardiovascular healthcare management system of claim 38 wherein the diagnostic engine includes algorithms for associating test results with possible diagnoses.

27. (Previously Presented) The cardiovascular healthcare management system of claim 38 wherein the diagnostic engine includes algorithms for associating diagnosis information with possible treatment plans.

28. (Previously Presented) The cardiovascular healthcare management system of claim 27 wherein the treatment plans include personalized drugs, diet and exercise suggestions.

29. (Canceled)

30. (Canceled)

31. (Canceled)

32. (Canceled)

33. (Canceled)

34. (Canceled)

- 35. (Canceled)
- 36. (Canceled)
- 37. (Canceled)

38. ( Previously Presented) A cardiovascular healthcare management system comprising:

- (a) an infomediary site having databases for cardiovascular healthcare management which includes a database of test results of concentration of subclasses of LDL particles and subclasses of HDL particles from at least 900 cardiovascular patients;
- (b) a data entry interface for receiving patient personal data and test results for concentration of subclasses of LDL particles and subclasses of HDL particles storing the data and results in the infomediary site databases;
- (c) a diagnostic engine for analyzing patient test results for subclasses of LDL particles, subclasses of HDL particles data and identifying patients who do not have hyperlipidemia based on total LDL cholesterol and total HDL cholesterol, but are in need of treatment; and
- (d) wherein the subclasses of LDL particles and subclasses of HDL particles are levels determined by segmented gradient gel eletrophoresis and wherein the particle sub-classes include HDL 2b.

For purpose of analysis, we focus on claim 38. Claim 38 is rejected under 35 USC § 103(a) based on a combination of these three patents Levin (U.S. 5,724,580); Otvos (U.S. 6,576,471) and Krause (U.S. 5,925,229).

In a previous Office Action, Applicant explained how the claimed invention differs from Levin, Otvos and Krause. The comments below expand on those differences as they more particularly relate to the claimed invention and how they alone or in combination fail to suggest the claimed invention to one of ordinary skill in the art.

Levin U.S. Patent 5,724,580

As acknowledged in the Office Action Levin does not disclose a data base with LDL subclasses and HDL subclasses. Levin does not recognize the LDL subclass and HDL subclass analysis can identify patients that have apparently normal LDL and HDL total values, which the whole point of the invention. Applicant's healthcare management system achieves this important health care advancement which was not known to exist in the prior art nor was it predictable. The expanded data unpredictability revealed the claimed relationship. Such a data base does not exist in the art and the results derived from such a data base are not obvious because it could not be determined if the claimed result even existed until applicant collected and analyzed the data base. Such a retrospective look at applicant's results and specification can not be the basis for obviousness. If anything Levin teaches away from applicants invention in that it only considers total HDL and LDL in the data base. For example, figure 25A of Levin provides:

LIPID PROFILE

Our records do not include any data on the lipid levels of patient. Since lipids are a major modifiable risk factor for CAD and its complications, we recommend obtaining LDL, HDL and triglyceride levels before the patient's next ischemia monitoring with Monitor One STRx. If these values are currently known, please report them to us.

Applicants claim a system that determines cardiovascular disease where total HDL and total LDL are normal. Levin does not suggest LDL subclass and HDL subclass data base and does not suggest the claim result. There is no suggestion to combine Levin with information found in Otvos and Krause.

Otvos U.S. Patent 6,576,471

Otvos describes determining some HDL and LDL subclasses by NMR. The limitation of NMR are described in the Shewmake Declaration in the Response of December 27, 2004. Thus NMR is not capable of accurately determining key subclasses such as HDL 2b. Otvos does not recognize the possibility of identifying patients with normal LDL and HDL who need treatment and the NMR technique is incapable of doing so. We note the applicant's claims are limited to gradient gel electrophoresis data for respective HDL and LDL subclass data in HDL 2b is a required subclass.

Krauss U.S. Patent 5,925,229

Krauss only describes the use of segmented gel electrophoresis to determine some LDL subclasses and does not describe the separation of HDL subclass. Krauss does not describe a data base of LDL subclasses or HDL subclasses. Krauss does not describe any HDL subclasses, much less the HDL 2b subclass present in the data base of the claimed health care management system.

In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. In re Avery (CCPA 1975) 518 F2d 1228, 186 USPQ 161. Obviousness cannot be established by combining the teaching of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In re Geiger (CAFC 1987) 815 F2d 686, 2 PQ2d 1276; In re Fine (CAFC 1988) 837 F2d 1071, 5 PQ2d 1596. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination, Berghauser v. Dann, Comr. Pats. (DCDC 1979) 204 uSPQ 393; ACS Hospital Systems, Inc. v. Montefiore Hospital (CAFC 1984) 732 F2d 1572, 221 USPQ 929. References which merely indicate that isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. In the present case, the references do not suggest the claimed element, as pointed out

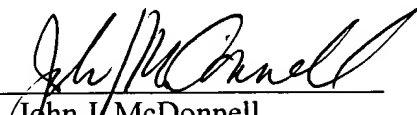
above. Ex Parte Hiyamizu (BPAI 1988) 10 PQ2d 1393. Where the references expressly teach away from what the PTO contends is obvious from the references, there is no basis for combination, In re Grasseli et al. (CAFC 1983) 713 F2d 731, 218 USPQ 769. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. In re Shaffer (CCPA 1956) 229 F2d 476, 108 USPQ 326, In re Skoll (CCPA 1975) 523 F2d 1392, 187 USPQ 481.

To properly combine references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in the references, or knowledge generally available to one of ordinary skill in the art, which would have led one to combine the relevant teaching of the two references. Ashland Oil Inc. v. Delta Resins and Refractories, Inc., et al. (CAFC 1985) 776 F2d 281, 227 USPQ 657; 5 PQ2d 1532. Both the suggestion to make the claimed process and the reasonable expectation of success must be founded in the prior art, not in applicant's disclosure. In re Vaeck (CAFC 1991) 20 USPQ 1938.

Absent Applicant's disclosure, there is no suggestion to combine Levin, Otvos and Krauss to provide a healthcare management system for identifying patients who do not have hyperlipidemia based on total LDL cholesterol and total HDL cholesterol, but are in need of treatment. Applicant's remarks are equally applicable to claims 22-28.

Allowance of claim 38 and 22-28 and passage of the case to issue are solicited.

Respectfully submitted,

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